BT/CT Import Export for Biological Products Under Development

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How do I import a material under development prior to having an IND?

Samples for testing purposes only

- **In process material**
  - **Permits CDC, USDA**
  - **Labeling**
  - **Get FDA involved early to facilitate Import**

How do I import a material for test development?

- **Samples for Research Use**
  - **Permits CDC, USDA**
  - **Labeling**

How can I import an Investigational New Drug (IND)?

Under an Investigational New Drug (IND) Application

- **IND in effect under 21 CFR 312.40**
- **Person receiving the investigational product is a listed investigator in a study submitted to and allowed to proceed under the IND**

How can I export an Investigational New Drug?

Under an Investigational New Drug (IND) Application

- **IND in effect under 21 CFR 312.40**
- **Person receiving the investigational product is a listed investigator in a study submitted to and allowed to proceed under the IND**
- **Study complies with the laws of the importing country**

How can I export an Investigational New Drug?

- **Under the 312 Program – 21 CFR 312.110**
  - **Foreign Government Request**
  - **Firm Request**

How can I export an Investigational New Drug?

Proposed Changes to 312 Program – Proposed Rule, published 6/19/02

- **Describe Drug (i.e., trade name, generic name, dosage form) and identify the countries**
- **Certification Process**

How can I export unapproved New Drugs and Biologics?

"Simple" Notification Process – 802(b)(1)(A)

- **Marketing authorization in a listed country (ies) will allow export anywhere**
- **Process – Section 802(g)**
  - **Notification to FDA when begin to export**
  - **Record-keeping**
    - **Marketing authorization**
    - **Distribution records**
    - **Labeling used**
  - **Meet conditions for export – Section 802(f)**

What are the conditions for export?

Conditions for export include – Section 802(f)

- **Substantial conformity with GMPs (or FDA-recognized international standards)**
- **Not otherwise adulterated**
- **Meets requirements of 801(e)**
- **Not an imminent hazard**
- **Labeled with requirements and conditions for use**
  - **in the country where it received valid marketing authorization, and**
  - **in the country to which it is to be exported, and**
  - **in the language and units of measurement to which it would be exported or language designated by such country**
- **Promoted as labeled**

How can I export unapproved New Drugs and Biologics?

Direct Export Process – Section 802(b)(2)

- **Drug complies with laws of foreign country**
- **Has valid marketing authorization**
- **FDA determines that the Foreign Country has certain statutory and regulatory requirements.**
- **Record-keeping**
    - **Marketing authorization**
    - **Distribution records**
    - **Labeling used**
- **Meet conditions for export – Section 802(f)**

How can I export unapproved New Drugs and Biologics?

Petition Process – 802(b)(3)

Appropriate health authority in foreign country

- **requests export approval**
- **certifies they understand the drug is not approved under the FD&C Act or by a listed country**
- **concurs that the scientific evidence provided to FDA is credible that the drug would be reasonably safe and effective in the foreign country**

FDA review of credible scientific evidence

Record-keeping - 802(g)

Meet conditions for export – Section 802(f)

Could the import for export provision be used to manufacture a product for export only?

This provision allows for the import of component not meeting the requirements of the FFDC Act if it is to be incorporated or further processed into a product that will be exported under the FFDC Act, or PHS Act – Section 801(d)(3)

Could the import for export provision be used to manufacture a product for export only?

Yes.

As Long as:

- **Your firm can meet the Import for Export provisions discussed in the previous slide, AND**
- **Your firm can meet the requirements of the chosen export mechanism**